DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

OFFICIAL FILE COPY

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: HEALTH CARE FINANCING ADMINISTRATION	1. TRANSMITTAL NUMBER: 04 - 06	2. STATE: TEXAS
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE: June 1, 2004	

5. TYPE OF PLAN MATERIAL *(Circle One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION: Section 1927 of the Social Security Act, as amended	7. FEDERAL BUDGET IMPACT: SEE ATTACHMENT a. FFY **2004** $ (212,175) b. FFY **2005** $ (1,369,123)
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: **SEE ATTACHMENT**	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: **SEE ATTACHMENT**

10. SUBJECT OF AMENDMENT:
This amendment adds program benefit agreements as an option to the supplemental rebate agreements for the Preferred Drug List for drug manufacturers or labelers.

Texas (04-06)
approved: 11/05/04
effective: 06/01/04

11. GOVERNOR'S REVIEW *(Check One)*:

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED:
Sent to Governor's Office this date. Comments, if any, will be forwarded upon receipt.

12. SIGNATURE OF STATE AGENCY OFFICIAL: D. Balland	16. RETURN TO: **David J. Balland** **Interim State Medicaid/CHIP Director** **Post Office Box 13247** **Austin, Texas 78711**
13. TYPED NAME: **David J. Balland**	
14. TITLE: **Interim State Medicaid/CHIP Director**	
15. DATE SUBMITTED: **6/30/04**	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 30 JUNE 2004	18. DATE APPROVED: 5 NOVEMBER 2004
PLAN APPROVED - ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: 1 JUNE 2004	20. SIGNATURE OF REGIONAL OFFICIAL: for Andrew J. Fredrickson
21. TYPED NAME: ANDREW J. FREDRICKSON	22. TITLE: REGIONAL ADMINISTRATOR DIV OF MEDICAID & CHILDRENS HEALTH
23. REMARKS:	

FORM HCFA – 179 (07-92)

E. Preferred Drug List: The state agency will consider a drug listed on the TDCI for inclusion in the PDL based on the following factors:

a) The recommendations of the Pharmaceutical and Therapeutics Committee (P&T committee);
b) The clinical efficacy of the drug consistent with the determination of the Food and Drug administration and the recommendations of the P&T committee;
c) Comparison of the price of the drug and the price of competing drugs to the Texas Medicaid outpatient drug program;
d) A program benefit offered by the manufacturer or labeler of the drug partially or wholly in lieu of a supplemental rebate and accepted by the state;
e) Written evidence offered by a manufacturer or labeler supporting the inclusion of a product on the PDL.

The state will examine information from any or all of these sources when considering the drugs to be included in the PDL.

The State will only include on the PDL drugs provided by a manufacturer or labeler that reaches an agreement with the state for supplemental rebates for drugs provided to Medicaid recipients. Manufacturers or labelers that offer a program benefit must first have a supplemental rebate agreement.

F. Supplemental Medicaid Drug Rebate Agreement: Pursuant to Section 1927 of the Act, the state has the following policies for Medicaid supplemental rebates and program benefits:

a) A model agreement between the state and a drug manufacturer for drugs provided to the Medicaid population, submitted to CMS on January 29, 2004, and entitled "Texas Health and Human Services Commission, Title XIX Vendor Drug Program, Supplemental Rebate Agreement", has been authorized by CMS.
b) Supplemental rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.
c) A model program benefit agreement between the state and the drug manufacturer for program benefits provided to the Medicaid program, submitted to CMS on September 14, 2004 and entitled "Texas Health and Human Services Commission Title XIX Vendor Drug Program Benefit Agreement" has been authorized by CMS.
d) Program benefits will consist of benefits, services, or expenditures that the State would otherwise bear under its state plan as medical or administrative expense.

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e) For program benefits, only the direct costs associated with the Program Benefit investment, including non-monetary benefits such as in-kind goods and services, in the program by the manufacturer or labeler will count as reducing the amount of the supplemental rebated owed. The savings or reduced claim experience that may result from the investment does not reduce the amount of the supplemental rebate owed.

f) Program benefits received by the state will be treated as supplemental rebates and will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement. For those manufacturers who have a Program Benefit Agreement, the State will determine the amount of supplemental rebate owed by the manufacturer at the end of a year. This amount represents 1) the potential total amount of Program Benefit investment by the manufacturer for the year, and 2) the basis for determining the amount of supplemental rebate that will be shared with the Federal government. For the CM64, the State will reduce its other Federal claims by the amount of the Federal share of the entire supplemental rebate owed at the end of the "Texas Health and Human Services Commission Title XIX Vendor Drug Program Supplemental Rebate Agreement" term.

g) Where the program benefit amount is less than the supplemental rebate amount, the program benefit amount plus the difference between the full supplemental rebate amount and the program benefit amount will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

G. P&T Committee: The P&T committee is established in accordance with §531.074 of the Texas Government Code, and will develop recommendations for preferred drug lists to be adopted by the state. The P&T committee is appointed by the governor and consists of six physicians and five pharmacists. The P&T committee shall meet at least quarterly to consider products in categories the state recommends for consideration. In developing its recommendations for a PDL, the P&T committee shall consider, for each product included in a category of products, the clinical efficacy, safety, cost-effectiveness and any program benefit associated with the product. The P&T committee shall inform the State Agency of its reasons for recommending drugs for the PDL. The P&T committee shall maintain confidentiality of information used in considering their recommendations including any information deemed confidential by law.

H. Public Notice: The State Agency will publish notice of the meetings of the P&T committee. The notices will include the categories to be considered at the upcoming meeting and instructions concerning filing of written comments and application to

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provide public testimony before the committee. The PDL will be published on the HHSC website. Within 10 days following the State Agency's decision on the recommendations of the P&T committee, the Agency will publish revisions to the PDL on the HHSC website.

I. No payment will be made for drugs in hospitals, nursing facilities and other institutions where those drugs are included in the reimbursement formula and vendor payments to the institution.

J. Expanded pharmacy benefits under EPSDT will end on the last day of the month in which the individual has his or her 21st birthday.

STATE Texas
DATE REC'D 6-30-04
DATE APPV'D 11-5-04
DATE EFF 6-1-04
HCFA 179 04-16

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